

R E M A R K S

The present application is in condition for allowance. Early and favorable action by the Examiner is respectfully solicited.

SUPPORT FOR CLAIM AMENDMENTS

Support for the amendments to the claims can be found in the drawings as originally filed, for example, in FIGS. 1, 2, 10, 11A, 11B, 12A, 12B and 19, and in the specification as originally filed, for example, on page 16, line 4-14, on page 23, lines 8-33, on page 25, lines 12-19, on page 30, lines 5-14, on page 31, line 27 through page 32, line 21, on page 33, lines 23-33 and on page 34, line 32 through page 35, line 11. As such, no new matter has been introduced.

CLAIM OBJECTIONS

The objection of claims 91 and 95 has been obviated by appropriate amendment and should be withdrawn.

CLAIM REJECTIONS UNDER 35 U.S.C. §101

The rejection of claims 83-98 under 35 U.S.C. §101, has been obviated by appropriate amendment and should be withdrawn. Claim 83 has been amended to recite generating a report for presentation on a display as suggested in the Office Action (see last two lines on page 3 and first two lines on page 4 of the

Office Action). Claims 90 and 94 recite a communications apparatus operable by an individual and, therefore, claim structure which is clearly tangible, concrete and useful. As such, the rejection under 35 U.S.C. §101 does not appear to be sustainable and should be withdrawn.

**CLAIM REJECTIONS UNDER 35 U.S.C. §112**

The rejection of claims 84, 85 and 90-98 under 35 U.S.C. §112, first paragraph, has been obviated by appropriate amendment and should be withdrawn.

The rejection of claims 83-98 under 35 U.S.C. §112, first paragraph, has been obviated by appropriate amendment and should be withdrawn.

The rejection of claims 87 and 94-98 under 35 U.S.C. §112, second paragraph, has been obviated by appropriate amendment and should be withdrawn.

Claim 83 recites steps of (i) after defining the groups, receiving genotype information for individuals in each of the groups, (ii) comparing the genotype information between the groups and (iii) generating a report for presentation on a display that represents a subset of the genotype information associated with each of the groups. Claim 90 recites whereby the genotype information is compared based upon groups formed using the responses to the scripted queries in the patient profile system to identify one or more individuals having a disease-influencing gene. Claim 94 recites whereby the genotype information of the at least

one individual is compared based upon groups formed using the responses and measurements to the scripted queries in the patient profile system to identify one or more individuals having a disease-influencing gene.

One skilled in the art relevant to the presently claimed invention would recognize the claims, when read in light of the specification, as containing subject matter which was described in the specification in such a way as to reasonably convey that the inventor, at the time the invention was filed, had possession of the claimed invention. Specifically, FIGS. 1, 2 and 13-20 along with the respective descriptive text would reasonably convey to the person of ordinary skill in the relevant art that the Applicant, at the time the invention was filed, had possession of the claimed invention. As such, the rejection under 35 U.S.C. §112, first paragraph with respect to the "written description" requirement does not appear to be sustainable and should be withdrawn.

Furthermore, the subject matter of the presently pending claims was described in the specification in such a way as to enable one skilled in the art to which it pertains or with which it is most connected, to make and/or use the claimed invention. Specifically, FIGS. 1, 2 and 13-20 along with the respective descriptive text does describe the subject matter of the presently pending claims in such a way as to enable one skilled in the art to which it pertains or with which it is most connected, to make and/or use the claimed invention. In particular, the specification provides numerous examples of genotype information and sources

(e.g., companies) from which genotype information can be received or obtained (see page 4, line 14 through page 9, line 25 of the specification). The specification further provides examples of comparing genotype information based on groups of individuals formed based upon responses to scripted queries. As such, the rejection under 35 U.S.C. §112, first paragraph with respect to the "enablement" requirement does not appear to be sustainable and should be withdrawn.

Furthermore, the Office Action states that Doberstein et. al. (U.S. Pub. No. 2003/0068649) supports the position that numerous difficulties are involved in relating gene sequences to other factors even using modern bioinformatics tools. A patent need not teach, **and preferably omits**, what is well known in the art (see M.P.E.P. § 2163(II)(A)(2), *In re Buchner*, 929 F.2d 660, 661, 18 USPQ2d 133 1, 1332 (Fed. Cir. 1991); *Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1384, 231 USPQ 81, 94 (Fed. Cir. 1986) (Emphasis added)). The fact that experimentation may be complex does not necessarily make it undue, **if the art typically engages in such experimentation** (*In re Certain Limited-Charge Cell Culture Microcarriers*, 22 1 USPQ 1165, 1174 (Int'l Trade Comm'n 1983), *aff'd. sub nom., Massachusetts Institute of Technology v. A.B. Fortia*, 774 F.2d 1104, 227 USPQ 428 (Fed. Cir. 1985)). As noted above, **the fact that experimentation may be complex does not necessarily make it undue, if the art typically engages in such experimentation.** The specification shows that the art does in fact

engage in such experimentation as routine business (see pages 6-8 of the specification). Doberstein et al. provides examples of various prior art techniques that use experimentation.

Assuming, *arguendo*, that numerous difficulties are involved in relating gene sequences to other factors even using modern bioinformatics tools (as suggested by the Office Action and for which Applicant's representative does not necessarily agree), it does not necessarily follow that such difficulties would render a person of ordinary skill in the relevant art incapable of comparing genotype information between groups of individuals, where the groups are formed using responses to scripted queries in the patient profile system, to identify one or more individuals having a disease-influencing gene, as presently claimed. As such, the rejection under 35 U.S.C. §112, first paragraph with respect to the "enablement" requirement does not appear to be sustainable and should be withdrawn.

Claims 84-89, 91-93 and 95-98 depend, directly or indirectly, from either claim 83, claim 90 or claim 94 which are believed to be allowable. As such, the presently claimed invention is fully patentable and the rejections should be withdrawn.

Accordingly, the present application is in condition for allowance. Early and favorable action by the Examiner is respectfully solicited.

The Examiner is respectfully invited to call the Applicant's representative at between the hours of 9:00 a.m. and

5:00 p.m. ET at 586-498-0670 should it be deemed beneficial to further advance prosecution of the application.

If any additional fees are due, please charge Deposit Account No. 50-0541.

Respectfully submitted,

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